IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BYRON SMITH, Individually and as Personal Representative of the Estate of India N. Smith, *et al.*	*	
v.	*	Civil Case No. CCB-12-1746
ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION, *et al.*	*	

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MEMORANDUM

Plaintiffs Byron Smith, individually and as personal representative of the estate of India N. Smith, and Carrie Youngbar, individually and as parent and next friend of India N. Smith, (collectively "Plaintiffs") have sued St. Jude Medical Cardiac Rhythm Management Division ("St. Jude") and Lifewatch Services, Inc. ("Lifewatch") for claims arising out of the death of their three-year-old daughter. St. Jude and Lifewatch have filed individual motions to dismiss the complaint. [ECF Nos. 14, 22]. The issues have been fully briefed, and a hearing was held on February 27, 2013. For the reasons articulated below, St. Jude's motion will be granted. Lifewatch's motion will be granted in part, and the case will be stayed pending Plaintiffs' compliance with the Maryland Health Care Malpractice Claims Act.

I. Factual Background

India Smith was born on June 30, 2005, to Byron Smith and Carrie Youngbar. Compl. ¶ 3. In her first few months of life, India was diagnosed with a serious heart condition. Compl. ¶ 12-13. She began treatment with Dr. Mubadda Salim, a pediatric cardiologist at the University of Maryland Medical School Department of Pediatric Cardiology. *Id.*

On November 4, 2005, doctors implanted India with a St. Jude Model 5380 Cardiac Pulse Generator ("the St. Jude pacemaker"). Compl. ¶ 14. At follow-up appointments, Dr. Salim noted that, because of India's particular condition, the ventricular threshold for pacing of her pacemaker was higher than the normal threshold. Compl. ¶ 17. Due to the increased threshold, the expected battery life of the pacemaker decreased from the anticipated "normal" battery life of four years down to two years. *Id.*

On May 3, 2007, India suffered cardiac symptoms, and doctors found a fractured ventricular lead in her pacemaker. Compl. ¶ 20. India underwent a lead replacement at this time. *Id.* Following the lead replacement, Dr. Salim noted that the ventricular capture rate of India's pacemaker had decreased. Compl. ¶ 23.

In late 2007, Dr. Salim explained to Plaintiffs that the pacemaker would signal when the battery had reached a level of depletion, thus indicating the need for replacement. *Id.* Dr. Salim noted that once the signal occurred, there still would be plenty of battery life remaining to allow for elective replacement of the pacemaker without endangering India. *Id.*

On May 12, 2008, Dr. Salim first discussed with Plaintiffs the timing to replace the battery in India's pacemaker. Compl. ¶ 25. Dr. Salim asked Plaintiffs to increase the frequency of the telephone interrogations of the pacemaker to every six weeks, but assured Plaintiffs that the pacemaker would continue to function as they evaluated when to schedule replacement of the battery. *Id.*

Six months later, on November 10, 2008, Dr. Salim told Plaintiffs that the pacemaker battery had a remaining useful life of about nine months. Compl. ¶ 26. Dr. Salim informed Plaintiffs that India would be scheduled in the next year for replacement of her pacemaker. *Id.* Dr. Salim also ordered monthly telephone interrogation of India's pacemaker by Lifewatch. *Id.*

Pursuant to Dr. Salim's order, Lifewatch was to call India's home every 30 days to interrogate her pacemaker over the phone to determine how it was functioning and how much battery life was remaining. *Id.*

On February 9, 2009, Dr. Salim noted that India had a normal physical evaluation. Compl. ¶ 28. He assured Plaintiffs that the pacemaker's battery had a life expectancy of about six months, and he anticipated replacement in late summer or early fall of 2009. *Id.* Dr. Salim continued to order monthly telephone monitoring of India's pacemaker by Lifewatch. *Id.* According to the complaint, however, Lifewatch's last monitoring call occurred on April 14, 2009. *Id.*

On May 11, 2009, Dr. Salim told Plaintiffs that the battery replacement likely would occur in September. Compl. ¶ 29. Dr. Salim again stated that India's needs would continue to be met by the pacemaker until then. Shortly after this appointment, when Plaintiffs arrived home, they received an urgent message from Dr. Salim's office. Compl. ¶ 30. By telephone, Dr. Salim explained that he had forwarded the latest interrogation results to the St. Jude company representative with whom he worked. *Id.* Based upon that conversation, Dr. Salim now believed that the remaining battery life on the pacemaker was much shorter than he had realized. *Id.* Dr. Salim requested to see India in early June to meet with the St. Jude representative and to schedule an elective battery replacement. *Id.*

On May 27, 2009, India died following a cardiac incident. Compl. ¶ 32. As part of the protocol for managing recently deceased pacemaker patients, hospital staff removed India's pacemaker and returned it to St. Jude for testing. Compl. ¶ 36.

According to the complaint, the pacemaker could not be tested at St. Jude until its battery was replaced. Compl. ¶ 37. Also according to the allegations in the complaint, investigative

reports by St. Jude and an autopsy performed on May 28, 2009 by the Office of the Chief Medical Examiner for the State of Maryland revealed that India's pacemaker stopped working due to a dead battery.[1] Compl. ¶ 39-40.

Plaintiffs allege that St. Jude and Lifewatch acted negligently, causing India's death. Plaintiffs also assert claims for breach of warranty against St. Jude. St. Jude has filed a motion to dismiss, claiming that Plaintiffs' claims are preempted under 21 U.S.C. § 360k(a) and *Riegel v. Medtronic*, 552 U.S. 312 (2008). Lifewatch also has filed a motion to dismiss, arguing that Plaintiffs have not complied with the requirements of the Maryland Health Care Malpractice Claims Act.

II. Legal Standards Governing Motions to Dismiss

The purpose of a motion to dismiss "'is to test the legal sufficiency of a complaint' and not to 'resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.'" *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243–44 (4th Cir. 1999)). To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court assumes the facts alleged in the complaint are true and draws all reasonable factual inferences in the nonmoving party's favor. *Edwards*, 178 F.3d at 244. A complaint need not provide "detailed factual allegations," but it must "provide the grounds of [the plaintiff's] entitlement to relief" with "more than labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555 (internal quotations omitted).

[1] St. Jude disputes this characterization of the reports' contents.

III. St. Jude's Motion to Dismiss

St. Jude contends that Plaintiffs' claims are federally preempted under 21 U.S.C. § 360k(a), the Medical Device Amendments ("MDA") to the Food, Drug, & Cosmetic Act. That law governs the Food & Drug Administration's ("FDA") regulation of medical devices. As the Supreme Court has noted:

> The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, FDA, Device Advice: Device Classes, *supra*. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii).

Riegel, 552 U.S. at 317. This court can take judicial notice, and the parties do not dispute, that the St. Jude pacemaker was approved as a Class III device following the FDA's pre-market approval ("PMA") process. Under the PMA process, the FDA undergoes a "rigorous regime" of considering the proposed product design, the manufacturing process, and the product labeling, including warnings. *Id.* at 317-18. Following the extensive review, which lasts "an average of 1,200 hours," the FDA weighs "the probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* at 318. "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.*

In *Riegel*, the Supreme Court considered claims that a Class III device, specifically a balloon catheter, had been designed, labeled, and manufactured in a manner that violated New York common law. *Id.* at 320. The Supreme Court found that, "Premarket approval . . . imposes 'requirements' under the MDA." *Id.* at 322. It further determined that, because of the extensive

regulation by the FDA, manufacturers who comply with the FDA-approved process for manufacturing the inherently dangerous Class III devices are not liable if a device is "defective" or fails to perform as expected. According to *Riegel*, the MDA expressly preempts all state law claims that differ from or add to the obligations or requirements imposed on the manufacturers by the FDA. *Id.* at 323-24. Specifically, the opinion in *Riegel* found preemption of claims for negligence, strict liability, and breach of implied warranty. *Id.* at 327-28.

a. Plaintiffs' Claims for Negligent Manufacturing and Breach of Implied Warranty of Merchantability

Plaintiffs' claims for negligent manufacturing and implied warranty appear to lie squarely within the scope of claims found to be preempted in *Riegel*. To attempt to distinguish their claims, Plaintiffs cite a narrow exception in *Riegel* allowing a State to provide "a damages remedy for claims premised on a violation of FDA regulations." *Id.* at 330. Such a claim is called a "parallel claim" because the state duties in question "'parallel,' rather than add to, federal requirements." *Walker v. Medtronic*, 670 F.3d 569, 577 (4th Cir. 2012) (citations omitted).

Plaintiffs, however, include no specific allegation of a violation of FDA regulations in the complaint, other than a conclusory allegation that India's pacemaker did not meet "FDA standards for reserve battery capacity." Compl. ¶ 55(a). The complaint does not indicate what, if any, "FDA standards for reserve battery capacity" were in place. In their opposition, Plaintiffs argue that the pacemaker failed to meet the standards set forth in the user's manual, *see* Opp'n 4-5, which indicates that the pacemaker has a nominal life of three months after reaching "ERI" (elective replacement indicator). St. Jude Mot., Ex. 3(b), at 40. The user's manual, however, also warns that the pacemaker may lose normal function "due to battery failure or component

malfunction." *Id.* at 14-15. Moreover, Plaintiffs allege no deviation from the prescribed PMA manufacturing process that would explain the alleged failure to meet the FDA standards.

Instead, without any factual allegations in support, Plaintiffs allege "that the Defendant St. Jude had a duty that required the sales and servicing support technicians . . . to advise Dr. Salim that the St. Jude model 5380 had a history of premature battery failure." Compl. ¶ 47. The complaint is devoid of factual allegations supporting any such history.[2] Plaintiffs further allege that "St. Jude had a duty to place in the stream of commerce a medical device that was properly functioning and was free from known defects, such as a defective battery." Compl. ¶ 48. However, "[a] common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*." *Walker*, 670 F.3d at 580. There is no allegation that the manufacturing of India's pacemaker deviated in any way from the process approved by the FDA, other than the conclusory allegation that St. Jude negligently failed "to manufacture a pacemaker that met FDA specifications for reserve battery capacity." Compl. ¶ 55(a). Such an allegation is insufficient. *See Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) ("Plaintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' in order to avoid preemption.") (quoting *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)). The fact that the St. Jude pacemaker allegedly failed does not itself establish a deviation from the FDA-approved standards. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (upholding dismissal of a complaint that does not "tell

[2] To the extent that this allegation is based on the information from the FDA website, there is no evidence that this history was sufficient to cause any recall or warning letter.

us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process").[3]

Plaintiffs cite the case of *Bausch v. Stryker*, 630 F.3d 546 (7th Cir. 2010), arguing that it runs contrary to the decisions of other circuits cited above. In *Bausch*, however, the plaintiff did not simply rely on conclusory allegations of a failure to comply with FDA requirements, but was able to cite to an FDA investigation into the approved device, an FDA product recall and a warning letter bearing a causal relationship to plaintiff's alleged injuries, and to a factual statement by the FDA suggesting that the device in question had not been manufactured in accordance with regulatory standards. *Id.* at 559. Plaintiffs provide no such factual support, in this case, for its allegation that St. Jude failed to comply with FDA requirements.[4] As a result, as pled, Plaintiffs' claims for negligent manufacturing and implied warranty are not supported by sufficient allegations to constitute a "parallel claim," and are therefore preempted.

b. Plaintiffs' Claims of Express Warranty and Negligent Misrepresentation

Plaintiffs contend that St. Jude is also liable for breach of express warranty and negligent misrepresentation arising out of information allegedly provided by a St. Jude representative to Dr. Salim. The complaint does not include any specific allegations regarding the content of what St. Jude may have communicated to Dr. Salim. The complaint merely states, "It is alleged that Salim and St. Jude gave express and implied warranties that the pacemaker battery that was

[3] There is some ambiguity as to whether the battery was in fact depleted. The cover letter accompanying the investigative reports from St. Jude indicates that the device needed a replacement battery to be properly tested. Opp'n Ex. 1. The report created by St. Jude, however, indicates that the battery was at ERI, and was therefore not at "end of life" as Plaintiffs allege. St. Jude Mot., Ex. 4. St. Jude argues that the cover letter was simply erroneous. Even if the facts are taken in the light most favorable to Plaintiffs, and it is assumed that the battery was depleted despite clear evidence to the contrary, Plaintiffs still have failed to plausibly allege that the device's failure was due to a deviation from FDA standards.

[4] At the hearing, Plaintiffs' counsel explained that he had not examined the pacemaker, which is in Plaintiffs' possession, to determine whether it had been opened to remove the battery, as the cover letter from St. Jude suggests. Nor had he directed an expert either to examine the pacemaker or to review the investigative reports from St. Jude, which appeared to demonstrate that the battery had not reached the end of its capacity to power the pacemaker.

implanted in India's body had several months of battery capacity left sufficient to allow scheduling her battery replacement on an elective basis sometime after June 2, 2009." Compl. ¶ 41.[5]

The claims involving the alleged communications between St. Jude and Dr. Salim fail under the "learned intermediary" doctrine. To state a claim for negligent misrepresentation, a plaintiff must allege a legal duty to provide the plaintiff with accurate information. *See, e.g., Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 136 (2007). Under FDA regulation and Maryland law, a device manufacturer owes no duty to provide information or warnings about a device to patients or consumers. *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94-95 (D. Md. 1989). Instead, the duty is owed to the prescribing physician, to allow the physician to provide case-specific information about the potential risks and benefits of proposed treatment to his or her patients. *Id.* The Fourth Circuit has recognized the specific need for the "learned intermediary" doctrine in the case of pacemakers, noting that "each pacemaker candidate presents different problems requiring individualized professional judgments." *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984). As such, St. Jude owed no duty to provide information or warnings directly to Plaintiffs, and Plaintiffs' claim for negligent misrepresentation must fail.

Although Plaintiffs repeatedly allege that Dr. Salim was acting as St. Jude's agent in conveying information to them, they provide no factual allegations to support any agent/principal relationship. It is implausible to suggest that a product manufacturer would ask a doctor to serve as its agent in communicating with that doctor's own patients, where the law requires no such direct communication. Plaintiffs' allegations therefore do not meet the requirement of *Twombly*, requiring sufficient facts to meet the standard of "facial plausibility." *Ashcroft v. Iqbal*, 556 U.S.

[5] At the hearing, Plaintiffs' counsel admitted that the content of the conversation between Dr. Salim and St. Jude is unknown.

662, 678 (2009). With their conclusory allegations of agency, Plaintiffs attempt to circumvent the learned intermediary doctrine and establish a direct duty between St. Jude and Plaintiffs. The law is clear, however, that no such duty existed.[6]

Moreover, Plaintiffs fail to allege that the St. Jude representative deviated from FDA requirements. The St. Jude representative allegedly stated, based on an inference from Dr. Salim's decision, that the pacemaker battery had sufficient battery capacity remaining to schedule the surgery in June 2009, yet the battery failed within days of that statement. *See* Compl. ¶ 41. Even assuming the St. Jude representative gave Dr. Salim an estimate regarding battery capacity, as explained more fully above, however, the fact that an FDA-approved battery allegedly failed does nothing to establish that St. Jude deviated from FDA-approved standards. *See Funk*, 631 F.3d at 782.

Plaintiffs also contend that St. Jude's representations to Dr. Salim create a cause of action for breach of express warranty. Maryland law allows an express warranty claim for "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Md. Code Ann., Com. Law I § 2-313(1)(a). The representations in question, however, happened almost four years after implantation of the device. The representations could not, therefore, have been part of the "basis of the bargain," and no express warranty claim is viable.

[6] In fact, the complaint states that Dr. Salim "explained that he had forwarded the latest interrogation results to the St. Jude company representative with whom he worked and that, based upon that conversation, *he* now believed that the remaining battery life on the pacemaker was much shorter than he realized." Compl. ¶ 30 (emphasis added). Plaintiffs have therefore pled that Dr. Salim spoke with St. Jude, and based on his independent medical judgment, Dr. Salim now believed that the pacemaker battery needed to be replaced in June rather than the fall of 2009. This scenario falls squarely within the learned intermediary doctrine.

c. Plaintiffs' Claims of Negligent Medical Care

Plaintiffs' complaint suggests that St. Jude had a duty to provide ongoing follow-up medical care and treatment to India. *See* Compl. ¶¶ 42-44, 46. As will be addressed in more detail below, however, medical malpractice claims against health care providers are subject to the Maryland Health Care Malpractice Claims Act. Plaintiffs have defined St. Jude not as a "health care provider," but as a "health care medical products manufacturing, sales, service, and consulting institution." Compl. ¶ 8. Plaintiffs' allegations of negligent medical care on the part of St. Jude do not meet the plausibility requirements of *Twombly*, as Plaintiffs have not adequately alleged facts to support any duty owed by St. Jude, a products manufacturer, to provide ongoing medical care.

IV. Lifewatch's Motion to Dismiss

Lifewatch seeks dismissal of Plaintiffs' claims for failure to comply with the Maryland Health Care Malpractice Claims Act ("MHCMCA"), Md. Code Ann. Cts. & Jud. Proc. § 3-2A-01 *et seq.* The MHCMCA requires, in relevant part, that medical malpractice claims be presented to the Maryland Health Claims Alternative Dispute Resolution Office ("the HCADRO") for mandatory arbitration before a court action may be filed. *Id.* at § 3-2A-02(a). Compliance with the arbitration requirement of the MHCMCA is a condition precedent to filing a diversity suit alleging medical malpractice in federal court. *See Lewis v. Waletzky*, 576 F. Supp. 2d 732, 738 (D. Md. 2008); *Davison v. Sinai Hosp. of Balt.*, 462 F. Supp. 778, 779 (D. Md. 1978).

The mandatory arbitration requirement applies to suits brought against a "health care provider for medical injury." Md. Code Ann. Cts. & Jud. Proc. § 3-2A-02(a)(1)(2005). The parties agree that Plaintiffs have filed claims under the MHCMCA against certain medical

providers involved in India's care. The parties disagree, however, about whether any such claim has been submitted against Lifewatch.[7]

Plaintiffs submit that they are uncertain whether or not Lifewatch qualifies as a "health care provider," suggesting that "some but not all facets of the service provided by Lifewatch involves [sic] rendering medical care." Opp'n 4. The allegations in Plaintiffs' complaint, however, are not equivocal. The complaint alleges that Lifewatch "owned, operated, managed or controlled a health care institution providing medical care and treatment to [India Smith] by and through its resident physicians, nurses, employees, servants and/or actual, apparent, or ostensible agents." Compl. ¶ 7. It further alleges that Lifewatch and its agents had a "duty to provide proper follow-up, diagnostic testing and evaluation, including but not limited to additional laboratory studies, radiological studies, and exploratory surgery to evaluate and treat obvious signs and symptoms of a failing pacemaker battery." Compl. ¶ 43.

A plain reading of the complaint indicates that Lifewatch was a health care provider and that its allegedly negligent employees included doctors and nurses. Plaintiffs now appear to suggest, in their opposition, that they may lack any factual basis for those allegations, and that Lifewatch may simply serve as a telephone monitoring system. Opp'n 5 ("In fact, however, if Lifewatch is simply a company providing a service that involves interrogating pacemakers over the telephone, they may not be a 'Health Care Provider' or 'related institution.'"). Taking the allegations in the complaint as written, the complaint includes both medical negligence claims and claims for negligent failure to monitor battery life. This court cannot conclude, therefore, that Plaintiffs' claims against Lifewatch fall outside of the scope of the MHCMCA.

[7] Plaintiffs assert that, "claims asserted against Lifewatch sounding in medical negligence are currently pending" in the HCADRO. Opp. 3, n.1. However, Lifewatch maintains that, "Plaintiffs never submitted the claims asserted against Lifewatch for mandatory arbitration" in the HCADRO. Lifewatch Mot. 6. At the hearing, Plaintiffs' counsel again asserted that the claims against Lifewatch (and indeed the claims against St. Jude) had been submitted to the HCADRO but arbitration had been waived.

At the hearing, Plaintiffs' counsel explained that they have filed their medical negligence claims against Lifewatch in the HCADRO. Accordingly, this case should be stayed pending the outcome of that proceeding. *See Jewell v. Malamet*, 587 A.2d 474, 481 (Md. 1991) (explaining that a stay, not dismissal, should be used to allow a plaintiff's compliance with the arbitration requirement). Plaintiffs may amend the complaint to reflect that they have complied with the requirements of the MHCMCA.

A separate Order follows.

Dated: March 13, 2013

_____/s/_____
Catherine C. Blake
United States District Judge